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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/928,467	08/13/2001	Spiridon Spireas	MPCI-0033	6452

7590            10/25/2004

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EXAMINER

WEBMAN, EDWARD J

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 10/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.	09/1928467	Applicant(s)	SPIRENS
Examiner	WEBMAN	Group Art Unit	1617

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

### Status

Responsive to communication(s) filed on 7/15/04.

This action is FINAL.

- Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

Claim(s) 83 - 86, 106 - 134 is/are pending in the application.

Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) 112, 121, 130 - 131 is/are allowed.

Claim(s) 83 - 86, 106 - 111, 113 - 120, 122 - 129, 132 - 134 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.  
 The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.  
 The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.  
 The specification is objected to by the Examiner.  
 The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119 (a)-(d)

- Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).  
 All  Some\*  None of the CERTIFIED copies of the priority documents have been received.  
 received in Application No. (Series Code/Serial Number) \_\_\_\_\_.  
 received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

### Attachment(s)

- Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_  Interview Summary, PTO-413  
 Notice of Reference(s) Cited, PTO-892  Notice of Informal Patent Application, PTO-152  
 Notice of Draftsperson's Patent Drawing Review, PTO-948  Other \_\_\_\_\_

## Office Action Summary

Art Unit: 1617

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 83-86, 106-111, 113-120, 122-129, 132-134 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/28255.

WO 98/255 teaches pretreating gabapentin hydrochloride in ethanol and recovering gabapentin hydrochloride (claim 10, 11). As to the claimed process steps, such are not considered patentable limitations during the prosecution of composition claims before the USPTO.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 83-86, 106-111, 113-120, 122-129, 132-134 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vilkov (US Patent No. 6,294,198 B1).

Vilkov teaches gabapentin processing with ethanol (title, abstract, column 5, lines 35-37), starch (column 6, line 20), and calcium stearate (column 6, line 14). A tablet is specified (abstract).

As to the claimed chloride, gabapentin is available as a chloride salt (see Satzinger et al. US Patent No. 4,087,544, column 2, line 10). It is well known in the art that the salt of an organic compound is more soluble than the organic compound itself.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the chloride salt of gabapentin as the active in Vilkov to achieve the beneficial effect of a more soluble active. The comment regarding process steps in the <sup>herein</sup> 102 is incorporated ~~4 grain~~.

Applicants argue that neither '255 nor Vilkov teaches mineral acid dispersed through the crystal structure. However, Both teach gabapentin-HCl crystals.

Claims 112, 121, 130-131 allowed.

Claims 83-86, 106-111, 113-120, 122-129, 132-134 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward Webman whose telephone number is (571) 272-0633. The examiner can normally be reached on Monday to Friday 9 AM 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, S. Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Webman/LR  
September 28, 2004



EDWARD L. WEBMAN  
PRIMARY EXAMINER  
GROUP 1617